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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/551,058

02/08/2007

Rajesh Jain

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EXAMINER

DICKINSON, PAUL W

ART UNIT

PAPER NUMBER

1618

NOTIFICATION DATE

DELIVERY MODE

05/23/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/551,058	Applicant(s) JAIN ET AL.	
	Examiner PAUL DICKINSON	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33,35-37 and 47-50 is/are pending in the application.
- 4a) Of the above claim(s) 48-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33,35-37 and 47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/17/2011</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's arguments, filed 3/14/2011, have been fully considered but they are not deemed to be fully persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objects are either reiterated or newly applied.

Response to Arguments

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection of claims 33, 35, 37, and 47 under 35 U.S.C. 103(a) as being unpatentable over US 5,614,222 ('222) is maintained.

Applicant argues that the Examiner has not met the initial burden to articulate reasoning with rationale underpinning to support the legal conclusion of obviousness. '222 discloses many different compounds. There is no suggestion of the use of two polymers as claimed in instant claim 33, and the Examiner pointing to these two polymers is based on impermissible hindsight.

Applicant's arguments have been fully considered but are not found persuasive. The rejection is based solely on the prior art and knowledge generally available to one of ordinary skill in the art. '222 discloses a rapidly

Art Unit: 1618

disintegrating oral controlled release pharmaceutical composition comprising amoxicillin trihydrate and a matrix material present in a core, wherein the core is coated with an enteric polymer. The matrix material may be a bioadhesive polycarbophil polymer (col 5, line 15) and the enteric polymer may be Eudragit L-100 (an acid insoluble methacrylic acid polymer) (col 5, line 57). The polymer system retards the release of the active ingredient in the stomach while providing rapid release in pH ranges above 5.5 (col 5, lines 22-32). Other pharmaceutically acceptable excipients may also be present (examples). '222 fails to disclose a specific combination of bioadhesive polycarbophil polymer and Eudragit L-100. However, it would have been obvious to one of ordinary skill in the art at the time the instant invention was made to prepare a composition according to '222 with bioadhesive polycarbophil polymer as the matrix material and Eudragit L-100 as the enteric coating material. The rationale for this is that '222 teaches that bioadhesive polycarbophil polymer may be the matrix material and Eudragit L-100 may be the enteric coating material. Upon reading '222, the ordinary artisan would understand that bioadhesive polycarbophil polymers are a preferred the matrix material and Eudragit L-100 is a preferred enteric coating material. Thus, arriving at this combination is no more than putting the components taught by '222 together in the manner instructed to by '222, that is, to incorporate polycarbophil polymer as the matrix material and to incorporate Eudragit L-100 as the enteric coating material, to prepare the stable aqueous drug suspension of '222. The Examiner's reasoning is based solely on the

Art Unit: 1618

teaching of '222 and knowledge generally available to one of ordinary skill in the art.

The rejection of claims 33, 35-37 and 47 under 35 U.S.C. 103(a) as being unpatentable over US 5,614,222 ('222) in view of US 6979735 ('735) is maintained.

Applicant argues that simply because '735 teaches clavulanic acid, this cannot be a basis for obviousness.

Applicant's arguments have been fully considered but are not found persuasive. '735 teaches that clavulanic acid is added to beta-lactam antibiotics, such as amoxicillin, to enhance the effectiveness of the drug (col 1, lines 11-29). Thus, it would have been obvious to add clavulanic acid to the composition of '222 to improve the anti-microbial effectiveness of amoxicillin. It is common in the pharmaceutical arts to add beta-lactamase inhibitors, such as clavulanic acid, to beta-lactam antibiotics, such as amoxicillin, because the beta lactamase inhibitors inhibit the microbe's beta-lactamases (i.e., the inhibitor hinders the microbe's resistance to the drug). For these reasons, it would have been obvious to add clavulanic acid to the composition of '222 to enhance the anti-microbial effectiveness of amoxicillin.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1618

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MICHAEL G. HARTLEY/
Supervisory Patent Examiner, Art Unit 1618

Paul Dickinson
Patent Examiner
Art Unit 1618

May 12, 2011